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STANDING OPERATING PROCEDURE
FOR
HOSTING AN EXTERNAL GOOD LABORATORY PRACTICES (GLP) INSPECTION

Preparer — Date: 03 JAN 2001

Supervisor Approval — Date: 1/4/2001

Annual Review

Preparer	03JAN02 Date Due	Date	Comp.
Supervisor	03JAN02 Date Due	Date	Comp.
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Disclaimer: This Standard Operating Procedure has been prepared for the sole use of the US Army Center For Health Promotion and Preventive Medicine (USACHPPM) and may not be specifically applicable to the activities of other organizations.

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U. S. Army Center For Health Promotion and Preventive Medicine
Strategic Initiatives Office (SIO), Quality Assurance Team (QAT)

STANDING OPERATING PROCEDURE
FOR
HOSTING AN EXTERNAL GOOD LABORATORY PRACTICES INSPECTION

CONTENTS

I. PURPOSE: This standard operating procedure describes the guidelines for hosting an external GLP inspection. This document will discuss in detail the duties of the QAT unit as well as other CHPPM employees when an external agency inspects CHPPM laboratories for compliance with GLP's.

II. APPLICABILITY: It is the policy of the USACHPPM that every effort is made to assure that all studies undertaken by TOX and the reports of such studies are of the highest possible quality and adhere to the best standards of professional scientific endeavor. It is the further the policy of USACHPPM that the regulations of the Food and Drug Administration (FDA) (21 CFR Part 58), the Environmental Protection Agency's (EPA) (40 CFR Part 160) and the Environmental Protection

Agency's (EPA) (40 CFR Part 792) for Good Laboratory Practices (GLP) in Nonclinical Laboratories be followed in every particular for all Toxicology Division (TOX) studies. To assist in implementation of this policy, a Quality Assurance Team (QAT) has been established as an integral and permanent organizational unit of USACHPPM. This SOP describes duties for the QAT office that are needed to assist in implementation of this policy.

III. DEFINITIONS: None

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IV. QUALITY CONTROL: This document shall be controlled in accordance with QSO 1.X

V. PROCEDURE:

1. Advance notice of agency inspections are submitted to the Quality Assurance Unit (QAT for CHPPM). The Head of the Quality Assurance Unit will notify the following people of the upcoming inspection:

a. Director, Toxicology
b. All DTOX Program Managers
c. Study Directors (indicate Studies to be inspected) and all appropriate personnel who may have been involved with the studies in question.
d. Director of Technical Services

2. If an inspection is unannounced, ask for a 1-2 day extension to schedule the inspection. If the request is not granted, allow the inspectors to stay in an appropriate area and notify people designated in item 1 above.

3. Initial contact with inspector(s) will be made by the Head of Quality Assurance who will serve as the Inspection Coordinator. If the Head of QA is not available, the Director of the Toxicology Department will designate a coordinator.

4. Inspectors will be asked to sign the CHPPM's Visitor's Log upon arriving and to indicate time leaving the site. Inspectors may be given a visitor's pass on each day of their visit.

5. The Inspection Coordinator will bring the inspector or inspection team to a selected conference room

and obtain the following information:

a. Identification of agency; EPA or FDA or both.
b. Personal identification of the inspector or inspection team and designation of team leader.
c. Written notice of inspection. FDA inspectors are required to present a written notice at the commencement of the inspection. EPA/FDA toxicology data audit inspectors are to provide lab management with an EPA drafted letter designating FDA authority to audit EPA records.
d. purpose of inspection.
e. Legal authority for the inspection. For example, 704(a) of FDCA, GLP inspection, EPA/FDA FIFRA toxicology data auditing program.
f. Date of inspection initiation and expected completion.
g. Outline of material proposed to be inspected, i.e. specific test articles, specific studies, raw data alone, facilities, etc.

6. During the inspection, a representative of the QAT will accompany the inspection team. Inspectors will not be permitted to use cameras or recording equipment during the inspection.

7. If prior notification has been received, the QAT staff will arrange to have all the appropriate information available for review in a designated conference room. If no prior notification has been received, the inspectors will remain in the designated conference room until the needed information can be obtained.

8. Inspectors will be requested to review one study at a time to preclude raw data mix-ups.

9. All information will be brought to the inspectors by QAT representatives. Inspectors will not be allowed to gain access to this material on their own. Inspectors may see and review our archive system but will not otherwise be allowed access to Archives.

10. Records for inspection:

Appropriate	Not Appropriate
Final Study Reports	Draft Reports
Protocols and Documentation of Adherence	Draft Pathology Notes
	Quality Assurance Audits

Raw Data Laboratory Worksheets	Interoffice Memos not study-specific
Slides and Tissues	Financial Information
Records of Maintenance and	Contract Documents
Calibration of Equipment	Cost Estimates
Curricula Vitae, Training	Correspondence prior to
Records, and Job Descriptions	Archiving

11. The Inspection Coordinator shall keep brief notes on the inspector's comments and important observations and should assure that any corrective actions that can be readily implemented during the inspection are completed.

12. The Inspection Coordinator shall retain duplicates of all copies of information requested by inspectors and shall ensure that all information that is "confidential" in nature shall be copied on paper which designates "Property of CHPPM" or "CHPPM Confidential".

13. Upon completion of the inspection, the Inspection Coordinator shall request a debriefing from the inspector(s) and request that a written audit report be submitted. The Coordinator should invite appropriate CHPPM Personnel to attend the debriefing meeting/exit conference.

14. The Inspection Coordinator will prepare a report on the inspection and submit it to the Directors of Toxicology and the Director of Technical Services.

VI. SAFETY CONSIDERATIONS: The inspector(s) will be given appropriate safety SOP's to review before inspecting any part of the facilities. The inspector(s) will adhere to all safety requirements of laboratory area being audited.

VII. REFERENCES:

1) USFDA Federal Food, Drug and Cosmetic Act (FFDCA); 21 CFR 58 (1979), latest edition.
2) USEPA Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); 40 CFR 160 (1984), latest edition.
3) USEPA Toxic Substances Control Act (TSCA); 40 CFR 792 (1983), latest edition.
4) DataChem Laboratories. Quality Assurance and Environmental/Occupational Health Monitoring. Salt Lake City, Utah: Dept. of Family and Preventive Medicine, 1991.
5) TBD Enterprises "Training by Design" handbook. Achieving a Competitive Edge With Good Laboratory Practices.